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09/913,444	08/15/2001	Koichi Ito	0425-0847P	9635

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EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 02/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/913,444</b>	Applicant(s) <b>Ito et al.</b>
Examiner <b>Bruck Kifle, Ph.D.</b>	Art Unit <b>1624</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jan 16, 2003

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)  Claim(s) 1-16, 24-26, 32, and 33 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-16, 24-26, 32, and 33 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6)  Other: \_\_\_\_\_

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/2002 has been entered.

Claims 1-16, 24-26, 32 and 33 are now pending in this application.

***Claim Rejections - 35 USC § 112***

Claims 1-16, 22-26, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

iii) The term “substituted” without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not. Page 32, line 7 to page 35, line 15 of the specification is noted. However, these groups are indicated to “include, but are not limited to” and, therefore, Applicants cannot rely on an open-ended list wherein the metes and bounds are not known. Also, some of the groups are further substituted for which the substituents are not known.

iv) The term “heteroaryl” is still indefinite because it is not known what kind of heteroatoms are involved.

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v) In the group “optionally substituted amide group”, R<sub>a</sub> and R<sub>b</sub> are defined as “hydrogen and C<sub>1-6</sub> allyl group”. It is unclear whether “alkyl” or “allyl” is intended. If “allyl” is intended, then the “C<sub>1-6</sub>” needs to be deleted because an allyl group is -CH=CH-CH<sub>3</sub>. Also, these groups should be linked with “or”.

Claims 24-26 are again rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating and ameliorating nerve degeneration diseases generally. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. Treating and ameliorating nerve degeneration diseases generally is *prima facie* not enabled because diseases such as Alzheimer’s disease, ALS, Parkinson’s, etc. are all embraced and these diseases vary widely in terms of cause and treatment. Applicants are asserting that they have succeeded where other have failed. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaeck 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

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Claim 33 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for preventing the diseases recited.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

- 1) The nature of the invention: The claim is drawn to prevention of diseases.
- 2) The state of the prior art: There are no known compounds of similar structure which have been demonstrated to prevent the diseases in claim 33.
- 3) The predictability or lack thereof in the art: It is presumed in the prevention of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop any kind of the disorders recited. There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.
- 4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one to protect a potential host from the disorders cited. There is no data present for the prevention of these disorders.
- 6) The breadth of the claims: The claims are drawn to disorders whose prevention is unknown.

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7) The quantity of experimentation need would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan for the many reasons stated above.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

Claims 1-16, 24-26, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Additional provisos have been included in the claims. This proviso lacks description. Even negative limitations require a description. The MPEP at 2173.05(i) Negative Limitations states “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli* , 231 USPQ 393 (Bd. App. 1983) aff'd mem., 738 F.2d 453 (Fed. Cir. 1984)” and, further, “Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.” In the instant case, the new concept that has been introduced by the proviso is the specific relationships between the variables. This specific relationship of connectivity was

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previously not disclosed. This notion that the definition of one variable depends on the definitions of other variables is new. The definition of a variable is no longer independent.

Applicants point out that the compounds excluded by proviso are taught in US 4,782,066 and US 4,670,555.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dekeyser et al. (US 4,670,555). The reference teaches structurally similar compounds. The claim differs by excluding compounds of the reference by proviso. However, compounds which are *prima facie* obvious over compounds of the reference are embraced by the claim. Thus, a prior art compound wherein R<sup>11</sup> is C2 chloroalkyl renders obvious a compound of the instant claim when R<sup>11</sup> represents a C3 chloroalkyl group.

It has been long established that structural relationship varying the size of a linking carbon chain - is *per se* obvious. Specifically, In re Shetty, 195 USPQ 753, In re Wilder, 195

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USPQ 426 and Ex Parte Greshem 121 USPQ 422 all feature a compound with a C<sub>2</sub> link rejected over a compound with a C<sub>1</sub> link. Similarly, In re Chupp, 2 USPQ 2nd 1437 and In re Coes, 81 USPQ 369 have a C<sub>1</sub> link unpatentable over a C<sub>2</sub> link. Ex parte Ruddy 121 USPQ 427 has a C<sub>3</sub> link unpatentable over a C<sub>1</sub> link. Ex parte Nathan, 121 USPQ 349 found the insertion of a C<sub>2</sub>H<sub>4</sub> link obvious. In all of these cases, the variation was per-se obvious and did not require a specific teaching.

Also, a prior art compound where R<sup>11</sup> is a C2 bromoalkyl renders obvious the compound of the instant claim where R<sup>11</sup> is a C2 iodoalkyl group because one halogen renders another halogen *prima facie* obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

February 4, 2003

  
Bruck Kifle  
Primary Examiner  
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